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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/929,663	KAMB ET AL.	
	Examin r	Art Unit	
	Jeffrey Fredman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-8 and 14-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-8 and 14-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

The rejection of claims 1, 2, 4 and 7 under 35 U.S.C. 102(e) as being anticipated by Mirabelli et al (U.S. Patent 5,639,595) are withdrawn in view of the amendment.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 2, 4, 7, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mirabelli et al (U.S. Patent 5,639,595) in view of Wong et al (J. Virol. (1994) 68(9):5523-5531).

Mirabelli teaches a method for identifying an agent (which is a perturbagen) that inhibits viral growth (column 4, lines 11-24), comprising the steps of:

a) introducing a perturbagen encoding nucleic acid in a vector scaffold into a cell (column 4, lines 11-16), b) exposing said perturbagen bearing cells to a virus (column 4, lines 16-18), c) selecting, in a manner as stringently as chosen, for growth proficient cells (column 4, lines 18-23 (also see claim 17)). Mirabelli also teaches the use of herpesvirus in the assay (column 26, claim 22). Mirabelli clearly indicates that the selected cells should be resistant to the infection, which inherently requires that the infection not be productive (see column 26, claim 17, step (e)).

Mirabelli does not teach screening for expressed proteins to identify functions or phenotypes, such as the viral growth inhibitory function.

Wong teaches a method of screening for a proteinaceous perturbagen comprising the steps: a) introducing a library of perturbagen encoding nucleic acids into a population of host cells (page 5525, column 2 and page 5526, figure 3), b) expressing the encoded proteinaceous perturbagens in said population of host cells (page 5525, column 2, page 5526, figure 3 and page 5527, figues 6 and 7), d) selecting for growth proficient cells (page 5525, column 2 and page 5529, table I), e) recovering from said growth proficient cells a sublibrary of nucleic acids encoding perturbagens that confer phenotype (page 5528, figure 8).

It is noted that claim 9 is broadly read to identify any cellular proliferation gene which is within the cell at the time of infection, such as the genes of Wong, and is not limited to host cell genes.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the method of Mirabelli with the method of

Wong since Mirabelli states "The cells are provided with conditions for growth and assayed for the phenotype conveyed by the desired activity. Cells which display this phenotype are then identified. (Column 4, lines 3-6)". Thus, an ordinary practitioner would have been motivated to use the method of Mirabelli to identify growth phenotypes using methods which permit identification of oligonucleotides which alter growth characteristics. The ordinary practitioner would have been motivated to combine Mirabelli with Wong since Wong states "Thus, the combination of a standardized high efficiency DNA transfection and retrovirus mediated gene transfer should facilitate the identification of genes capable of conferring to target FD cells a detectable new function or phenotype. By scaling up the size of the experiment realistically during screening, the assay can detect cDNA at an abundance of lower than 0.0001% (abstract)". An ordinary practitioner would have been motivated to use the screening method of Wong with the viral perturbagen assay of Mirabelli in order to identify proteins which function to enhance growth in the presence of viruses, since Wong expressly suggests the method for use in detecting new functions and phenotypes and for the advantages of high efficiency transfection, sensitive detection of low abundance nucleic acids and standardization.

4. Claims 1-4, 6, 7, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mirabelli et al (U.S. Patent 5,639,595) in view of Wong et al (J. Virol. (1994) 68(9):5523-5531) and further in view of Ha et al (Mol. Biochem. Parasitol. (1996) 77:57-64).

Mirabelli in view of Wong teach the limitations of claims 1, 2, 4, 7, 14 and 15 as discussed above. Mirabelli in view of Wong do not teach GFP protein scaffolds.

Ha teaches the use of GFP as a scaffold for the presentation of the LPG1 protein in screening assays where cells are screened using GFP-LPG1 fusion proteins and sorted by FACS into either high or non-fluorescent groups (abstract, page 60, subheading "FACS analysis of GFP expression")

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the method of Mirabelli with the use of GFP fusion proteins as taught by Ha since Ha states "GFP can be readily used to monitor gene expression in several cellular compartments and is active when expressed as N- or C- terminal fusions. Moreover, GFP is compatible with other fluorescent markers, and does not require other co-factors or cell-type or species-specific modifications for fluorescence (page 58, column 1)". An ordinary practitioner would have been motivated to utilize the GFP fusion proteins in the method of Mirabelli to identify analyze the diversity of the Mirabelli library and because GFP is readily used to monitor expression in a non cell or species specific way.

5. Claims 1, 2, 4, 7, 8, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mirabelli et al (U.S. Patent 5,639,595) in view of Wong et al (J. Virol. (1994) 68(9):5523-5531) and further in view of Rubin et al (WO 97/39119).

Mirabelli in view of Wong teach the limitations of claims 1, 2, 4, 7, 14 and 15 as discussed above. Mirabelli in view of Wong do not teach screening for agents which affect HIV infection.

Rubin teaches screening for cellular components which affect HIV infection (page 6).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the method of Mirabelli in view of Wong with the use of HIV and other equivalent viruses as taught by Rubin since Rubin expressly demonstrates the equivalence of HIV to other viruses in screening methods, including to the herpsevirus taught by Mirabelli. As MPEP 2144.06 notes "An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout , 675 F.2d 297, 213 USPQ 532 (CCPA 1982)." Here, the prior art expressly recognizes the equivalence of the viruses in the screening assay methodologies, and an ordinary practitioner would have been motivated to substitute equivalents in order to identify inhibitors of HIV as taught by Mirabelli, as well as the expressly taught inhibitors of herpesviruses.

6. Claims 1, 2, 4, 7 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mirabelli et al (U.S. Patent 5,639,595) in view of Wong et al (J. Virol. (1994) 68(9):5523-5531) and further in view of Fields et al (U.S. Patent 5,283,173).

Mirabelli in view of Wong teach the limitations of claims 1, 2, 4, 7, 14 and 15 as discussed above. Mirabelli in view of Wong do not teach the use of the two hybrid system.

Fields teaches the use of a two hybrid system (abstract).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the method of Mirabelli in view of Wong with the use of a two hybrid system of Fields since Fields states "One advantage of this

method is that a multiplicity of proteins can be simultaneously tested to determine whether any interact with a known protein (column 3, lines 40-42)". An ordinary practitioner would have been motivated to test a protein recovered by the method of Mirabelli in view of Wong using the two-hybrid system of Fields in order to identify proteins which interact with the recovered protein in order to characterize the pathway of viral resistance as expressly motivated by Fields.

Response to Arguments

7. Applicant's arguments filed May 28, 2003 have been fully considered but they are not persuasive.

Applicant argues the 103 rejection of Mirabelli in view of Wong by stating that the references do not teach an element of the claims, specifically the presence of a library of nucleic acids. Applicant incorrectly states that the examiner recognizes this deficiency. The use of libraries for screening is expressly taught by Wong. Wong states "In this report, we establish a method with which a growth-stimulating gene can be detected from a library of plasmid DNA consisting of at least 100,000 independent clones (page 5524, column 1)." This is an express teaching by the secondary reference regarding the use of libraries. With regard to the placement of the perturbagen into a scaffold, that element is taught by Mirabelli. Therefore, the 103 rejection of Mirabelli in view of Wong remains applicable.

Applicant relies upon overcoming Mirabelli in view of Wong in order to overcome the other 103 rejections. Since that rejection is maintained, so are the other 103 rejections.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Jeffrey Fredman
Primary Examiner
Art Unit 1634

July 11, 2003